



Food and Drug Administration
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May 7, 2015

Insightra Medical Incorporated
Mr. Neerav Parikh
Regulatory Affairs and Quality Assurance Specialist
9200 Irvine Center Drive, Suite 200
Irvine, California 92618

Re: K142192
Trade/Device Name: Freedom Ventral Hernia Repair System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTL, OXJ
Dated: April 3, 2015
Received: April 7, 2015

Dear Mr. Parikh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142192

Device Name

Freedom Ventral Hernia Repair System

Indications for Use (Describe)

The Insightra Freedom Ventral Hernia Repair System is intended for use in the open repair of ventral hernias.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) Summary

This 510(k) Summary is provided per the requirements of section 807.92(c).

Date: May 6, 2015

Submitter Information:

Submitters Name: Insightra Medical Inc.
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Device Name:

510(k) Number: K142192
Trade Name: Freedom Ventral Hernia Repair System
Common/Usual Name: Surgical Mesh
Classification Name: Surgical Polymeric Mesh
Classification Code: Class II, § 878.3300, Product Code FTL

Predicate Devices:

- Atrium Prolite Mesh, K002093, FDA cleared on 7/24/2000
- Covidien Surgipro Mesh, K905655, FDA cleared on 12/31/1990

Device Description:

The Insigntra Ventral Hernia Repair System is composed of a polypropylene woven mesh implant and a disposable Strap Passer accessory that is used during the surgical implantation. The mesh implant is an oval shape with 8 straps that extend radially from the oval portion. The straps are used to secure the mesh to the implantation site, similar to traditional methods such as suturing or stapling. During the implantation procedure, the straps are then trimmed below the skin and become incorporated in the muscle tissue.

Intended Use:

The Insigntra Freedom Ventral Hernia Repair System is intended for use in the open repair of ventral hernias.

Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use:

The Insigntra Freedom Ventral Hernia Repair System and the predicate devices have similar technological characteristics. Specifically, the Insigntra Freedom Ventral Hernia Repair System and the predicate devices are all designed as surgical polypropylene mesh devices to be used to support soft tissue during hernia repair. These devices are available in a variety of configurations available to accommodate the various patient anatomies and hernia defect types.

The Insigntra Freedom Hernia Repair System differs from the predicate devices with the use of the Strap Passer. The Strap Passer is used during the surgical implantation procedure to pass the straps of the implanted mesh through the abdominal wall muscle. The straps are then trimmed below the level of the skin. The straps, used in this manner, provide an equivalent method of securing the mesh to the implantation site as compared to the predicate devices which use sutures, staples, or tissue anchors for attaching the mesh to the muscle tissue.

There are no new types of safety or effectiveness questions due to the surgical implantation procedure for these types of devices and scientific methods exist for the evaluation of the new characteristics. Performance data provided in this premarket notification demonstrate substantial equivalence between the Insigntra Freedom Ventral Hernia Repair System and the predicate devices.

Performance Data:

Biocompatibility testing in accordance to ISO 10993-1 standards was conducted and the results indicate that the device is biocompatible per these standards.

Bench testing results and in vivo simulated use experiments demonstrate that the proposed device design meets product specifications and intended use. In support of this submission, whole system simulated use testing was conducted in fresh porcine meat to ensure that the proposed Freedom Ventral Hernia Repair System user needs. The animal testing was also conducted per GLP requirements.

All test results provided in this submission support the safety and effectiveness of the device for its intended use utilizing the least burdensome approach and demonstrate that the proposed device is substantially equivalent to its predicate devices.

Conclusions Drawn from Clinical Studies:

The Freedom Ventral Hernia repair was an effective repair in terms of recurrence rates, lack of migration and acute pain rates. The Freedom Ventral Hernia Repair system enables broad margin coverage in the preperitoneal sublay and retromuscular sublay position. The results of testing demonstrate that the Freedom Ventral Hernia Repair is substantially equivalent to the predicate devices in design, function, and indications for use.